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MEMORANDUM

To: Members of the Subcommittee on National Security, Emerging Threats, and International Relations

From: Kristine K. McElroy

Subject: Briefing Memorandum for the hearing, *Assessing Anthrax Detection Methods* scheduled for Tuesday, April 5, 2005, at 2:00 p.m. in room 2154 Rayburn House Office Building.

PURPOSE OF THE HEARING

The purpose of the hearing is examine the steps federal agencies have taken to detect anthrax contamination (particularly in federal facilities), analysis of test results, efforts to validate detection protocols and any improvements in detection methodology.

HEARING ISSUES

1. **Who is in charge of anthrax detection and the validation process?**
2. **What barriers have prevented validation?**

BACKGROUND

The science behind anthrax detection results is limited. Detection methods have not been validated and therefore one cannot place too much confidence in the accuracy of the results. More than three years after the 2001 anthrax incidents one cannot say if those facilities are completely free of anthrax contamination. However, agencies believe there is little risk now since the samples taken were negative, and no one has presented with symptoms. **(Attachment 1)**

Uncertainty also remains regarding what agency is responsible for promoting the validation of anthrax detection. Validation is especially important since science still does not know what the lethal dose of anthrax for a particular individual is and since anthrax spores are hardy they can last for years to come. **(Web Resource 1, p. 13)**

GAO Report

The General Accounting Office (GAO) will release a report at the hearing entitled, "Anthrax Detection: Agencies' Validating Detection Methods Would Improve Confidence In Negative Results." The hearing will focus on the findings of this report.

"Validation is a formal, empirical process in which an authority determines and certifies the performance of a given method." **(Attachment 1)** Anthrax testing done in postal facilities in 2001 was not validated. According to the draft GAO report, "the lack of validation of their activities, coupled with limitations associated with their targeted sampling strategy, means that there can be little confidence in the reliability of the negative test results." **(Attachment 1)**

There are several steps involved in the environmental sampling process. They include sampling strategy development, sample collection, transportation, extraction and analysis of the samples. These steps have not been validated for anthrax testing. **(Attachment 1)**

A sampling strategy includes deciding how many samples to collect, where to collect them from and what collection methods to use. The agencies involved in the United States Postal Service (USPS) 2001 anthrax

incident chose a targeted strategy. **(Attachment 1)** Targeted sampling tends to be quicker and inexpensive since it focuses on a particular area instead of ensuring the entire area is tested and there are fewer samples taken. However targeted sampling can be affected by bias and is not a reliable method in deterring the true extent of contamination. **(Web Resource 2)**

The agencies collected samples from specific areas, such as the mail processing area since they were determined to be the most likely places where anthrax would be. However, according to GAO, "Without probability sampling, inferences about a facility's status-that is, whether it was contaminated could not be reliably based on negative results." **(Attachment 1)**

Probability sampling is based on random selection therefore each item in a population has an equal probability of being chosen. **(Web Resource 2)** When negative results are achieved through probability sampling one can have confidence about the specific level of contaminant in a population. **(Attachment 1)**

According to the agencies, targeted sampling was used instead of probability sampling because they were limited in the number of samples they could collect since laboratory analytic capacity was limited. **(Attachment 1)** The agencies and their contractors used different methods to collect samples. USPS used dry swabs to collect samples for the most part, even though these were known to be the lease effective method. CDC and EPA used dry swabs, wet swabs, wet wipes and a high-efficiency particulate air (HEPA) vacuum.

After collecting samples, the agencies had to transport the samples. They followed federal regulations for transporting "infectious substances" however, these guidelines are meant to prevent an unintentional release of anthrax rather than ensure the samples' biological reliability for testing. It is not known if the anthrax spores were affected by the transportation in terms of their viability (ability to divide and multiply). The effect of temperature and light on spores during transportation has not been studied. Culture analysis is dependent on the spores ability to divide and multiply so tests can determine whether a sample contains anthrax. **(Attachment 1)**

After transportation, laboratory personnel need to extract the particles from sample material, using extraction fluids and other lab procedures.

However, because no sample extraction efficiency data was available, interpreting anthrax analytic results was problematic. **(Attachment 1)**

After extraction, the material must be analyzed. However, knowledge about the limits of detection for field-based tests was deficient because there were not enough trained personnel to use these methods. **(Attachment 1)**

GAO recommendations

The GAO report will recommend the Secretary of Homeland Security work with agencies to ensure validation studies of sampling process activities and methods be conducted. Specifically, the GAO will recommend the Secretary should:

1. take a lead role in promoting and coordinating the activities of the various agencies that contain the technical expertise related to environmental testing;

2. ensure that a definition of validation is developed and agreed on;

3. guarantee that the overall process of sampling activities, including methods, is validated so that performance characteristics, including limitations, are clearly understood and results can be correctly interpreted;

4. see that appropriate investments are made in empirical studies to develop probability-based sampling strategies that take into account the complexities of indoor environments;

5. ensure that appropriate, prioritized investments are made for all biothreat agents; and

6. make sure that agency policies, procedures and guidelines reflect the results of such efforts. **(Attachment 1)**

Laboratory Response Network (LRN)

The Laboratory Response Network was established in 1999 by the Centers for Disease Control and Prevention. The mission of the LRN is to "maintain an integrated national and international network of laboratories that are fully equipped to respond quickly to acts of chemical or biological terrorism, emerging infectious diseases, and other public health threats and emergencies." **(Web Resource 3)** There are 149 laboratories in the LRN. **(Attachment 2, p. 2)** The LRN includes state and local public health, veterinary, military and international labs. Labs operated by the Department of Defense include the Naval Medical Research Center in Bethesda, MD. **(Web Resource 3)**

DOD Anthrax Scare

The most recent anthrax scare at the Department of Defense (DOD) postal facilities continues to show the weaknesses in responding to a biological incident. It is believed that samples were mixed up in a Defense contractor's laboratory. A senior military official stated, "quality control problems" at a contractor's laboratory appeared to have caused the false alarm. **(Attachment 3, p. 1)**

Evidenced suggested that a lab anthrax sample used to calibrate equipment may have contaminated an air filter at the Pentagon shipping center that had been sent to a private laboratory for routine testing on Thursday, March 10, 2005. **(Attachment 2, p. 2)** This contaminated sample was then sent for a confirmation test to the army biodefense laboratory at Fort Detrick. The laboratory confirmed the positive test on Tuesday, March 15. **(Attachment 3, p. 1)**

According to Scott J. Becker, executive director of the Association of Public Health Laboratories, "The Department of Defense appears to be developing their own detection systems…The linkages to public health just didn't seem to be there. Clearly, things broke down." **(Attachment 2, p. 1)**

Local hazardous material teams were not familiar with sensor equipment used by DOD since it was different than the equipment used by the Postal Service and the Department of Homeland Security." **(Attachment 2, p. 1)** Lab practices at the DOD facilities differed from private laboratories, making it difficult to interpret the data. **(Attachment 2, p. 3)**

Scientists had difficulty understanding the DOD contract lab findings since the lab is not a part of the Laboratory Response Network (LRN). **(Attachment 2, p. 1)**

The DOD has recently had an "after-action" review of the anthrax scare and has decided to require test results from biological sensors be reported within 24 hours instead of the three days it took to get results from the private contractor. DOD will also move toward aligning laboratory testing protocols with the CDC and to move away from using the contract laboratories. DOD will also work closer with local health officials when requesting emergency medical treatment for workers. **(Attachment 4, p.1)**

DISCUSSION OF HEARING ISSUES

1. Who is in charge of anthrax detection and the validation process?

The GAO recommends the Secretary of Homeland Security work with agencies to "ensure that appropriate validation studies of the overall process of sampling activities including the methods, are conducted." **(Attachment 1)** GAO believes the DHS Secretary needs to take the lead role in ensuring this coordination take place. However DHS comments to GAO on the draft report suggest an unwillingness on the part of DHS to take the lead in this area. DHS states:

> Overall responsibility for coordination has been charged to the Secretary of DHS for future biological attack. However, the lead agencies responsible are outlined in the NPR and HSPD-10. They clearly assign the EPA with the primary responsibility of establishing the strategies, guidelines, and plans for the recovery from a biological attack while HHS has the lead role for any related public health response and guidelines." **(Attachment 5, p. 2)**

Congress had directed the Environmental Protection Agency (EPA) to "enter into a comprehensive MOU with DHS by August 1, 2005 that will define the relationship and responsibilities of these entities with regard to the protection and security of our Nation. The conferees expect the MOU to specifically identify areas of responsibilities and the potential costs (including which entity pays, in whole or part) for fully meeting such

responsibilities. EPA shall submit to the House and Senate Committees on Appropriations a plan no later than September 15, 2005 that details how the agency will meet its responsibilities under the MOU, including a staffing plan and budget." **(Attachment 6, p. 1)**

2. What barriers have prevented validation?

The process of validation requires replication and can therefore be an expensive and timely process. DHS states, "the first steps towards validation must involve defining the necessary requirements for the sampling process and developing standards from those requirements…the standards development process relies on consensus building, an activity that is often time-consuming and costly." **(Attachment 5, p. 2)**

The Association of Public Health Laboratories (APHL) states, "While no credible scientist would disagree that validation of methods used for scientific purposes, such as those used for reliable detection of the anthrax bacillus, is always the best practice, in reality, under the weight of the situation that fall, [October 2001] and with the critical need for rapid action, there was no time for validation." **(Attachment 7, p. 1)**

Should another anthrax incident occur in the future agencies will be faced with the same limitations they were in 2001 in not being able to guarantee an area is free from anthrax contamination since anthrax detection has not been validated. Some believe this is far too great a risk to take since science has not determined the lethal dosage of anthrax.

Mr. Keith Rhodes, Chief General Accounting Office Technologist, Government Accountability Office, will testify about the GAO report entitled, "Anthrax Detection: Agencies' Validating Detection Methods Would Improve Confidence In Negative Results."

Ms. Tanya Popovic, Associate Director for Science, Centers for Disease Control and Prevention will testify about the role CDC plays in anthrax detection and the Laboratory Response Network.

The Department of Defense will provide a witness to testify about the anthrax incident in Virginia, the lessons learned and anthrax detection.

Ms. Dana Tulis, Deputy Director for the Office of Emergency Management, Environmental Protection Agency will testify about the role EPA plays in anthrax detection.

Dr. Katherine Kelley, Director for the Department of Public Health Laboratory will testify about the role the public health laboratories play in anthrax detection.

Mr. Thomas G. Day, Vice President of Engineering, United States Postal Service will testify about the status of anthrax detection in postal facilities.

Mr. William Burrus, President of the American Postal Workers Union, AFL-CIO will testify about the status of anthrax detection in postal facilities.

Dr. Linda D. Stetzenbach will testify about the state of the art of sampling and validation of sampling protocols.

Mr. James H. Schwartz, Chief, Arlington County Fire Department will testify about his experience with March 14 anthrax scare and local responder concerns.

Mr. Michael P. Neuhard, Chief, Fairfax County Fire Rescue Department will testify about his experience with the March 14 anthrax scare and local responder concerns.

Mr. Phillip Schaenman, President, Tridata Division of System Planning Cooperation will testify about the "after action" review of the DOD March 14 anthrax scare.

ATTACHMENTS

1. Highlights page to accompany draft GAO report entitled "Anthrax Detection: Agencies' Validating Detection Methods Would Improve Confidence In Negative Results" GAO-05-251.

2. Spencer HsU, "Anthrax Alarm Uncovers Response Flaws" *The Washington Post,* March 17, 2005.

3. Scott Shane, "Anthrax Scare Is Attributed to a Testing Error" *The New York Times*, March 16, 2005.

4. Spencer Hsu, "Biohazard Procedures to Change: Officials Acknowledge Anthrax Scare Missteps" *The Washington Post,* March 27, 2005.

5. Department of Homeland Security comments on GAO draft report entitled "Anthrax Detection: Agencies' Validating Detection Methods Would Improve Confidence In Negative Results," GAO-05-251, February 18, 2005.

6. Congressional Record- House, November 19, 2004. p. H10850

7. Association of Public Health Laboratories comments on the draft GAO report entitled "Anthrax Detection: Agencies' Validating Detection Methods Would Improve Confidence In Negative Results," GAO-05-251, February 23, 2004.

WEB RESOURCES

1. Subcommittee Hearing Transcript for Heating entitled, "STAMPING OUT ANTHRAX IN USPS FACILITIES: TECHNOLOGIES AND PROTOCOLS FOR BIOAGENT DETECTION" MAY 19,2003
http://frwebgate.access.gpo.gov/cgiin/getdoc.cgi?dbname=108_house_hearings&docid=f:89545.wais

2. Non-Probability Sampling website
http://www.statcan.ca/english/edu/power/ch13/non_probability/non_probability.htm

3. CDC website on Laboratory Response Network (LRN)
http://www.bt.cdc.gov/lrn/factsheet.asp